consists of primary particles having a diameter less than or equal to about 10 microns[, said primary particles optionally being formed into agglomerates].

2. (Amended) A [pharmaceutical] composition as claimed in claim 1, <u>including said one or more non-hygroscopic additives,</u> said [composition additionally] <u>one or more non-hygroscopic additives</u> comprising a [pharmaceutically acceptable] carrier, which comprises either

(a) particles having a diameter of less than about 10 microns, such that at least 50% of said composition consists of [optionally agglomerated] primary particles having a diameter of less than about 10 microns; or

(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between [the active compounds and] <u>(i)</u> the carrier <u>and (ii) the polypeptide of (A) and the one or more surfactants of (B)</u>.

12. (Amended) The composition of claim [11] <u>1</u>, wherein said surfactant is a bile salt, a bile salt derivative, an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.

13. (Amended) The composition of claim [11] <u>1</u>, wherein said surfactant is a salt of a fatty acid.

16. (Amended) The composition of claim [11] 1, wherein said surfactant is sodium caprate.

21. (Amended) A method for systemic administration of a [pharmaceutically] biologically active polypeptide, comprising

providing a composition comprising a mixture of active compounds (A) a [pharmaceutically] biologically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of the polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device; and

causing said patient to inhale through the mouth said composition from a dry powder inhaler device; provided that at least 50% of the total mass of the active compounds, at the point the active compounds enter the respiratory tract of the patient, consists of particles having a diameter less than or equal to about 10 microns.

31. (Amended) The composition of claim 1, wherein at least one of said [enhancer compound] one or more surfactants is a bile salt.

50. (Amended) The method of claim 21, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine,

enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade[, that exerts its pharmacological effect systemically].

56. (Amended) The method of claim [21] 28, wherein said surfactant is a bile salt, a bile salt derivative, an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.

61. (Amended) A [pharmaceutical] composition, comprising

a mixture of active compounds (A) a [pharmaceutically] biologically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates; and

a [pharmaceutically acceptable] carrier comprising particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.

64. (Amended) The composition of claim 61, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade[, that exerts its pharmacological effect systemically].

76. (Amended) The composition of claim 61, wherein [aid] said enhancer compound is a bile salt.

78. (Amended) A dry powder inhaler device containing a [pharmaceutical] composition comprising a mixture of active compounds (A) a [pharmaceutically] biologically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates; the dry powder inhaler device being adapted for inhalation through the mouth.

79. (Amended) The dry powder inhaler device of claim 78, wherein the [pharmaceutical] composition comprises a [pharmaceutically acceptable] carrier, which comprises either

(a) particles having a diameter of less than about 10 microns, such that at least 50% of said composition consists of optionally agglomerated primary particles having a diameter of less than about 10 microns; or

(b) particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.

F13 cont

82. (Amended) The dry powder inhaler device of claim 78, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade[, that exerts its pharmacological effect systemically].

F14

Add new claims 101 as follows.

F15

--101. The composition of claim 1, wherein the primary particles are agglomerated.--

REMARKS

Claims 1-10, 12-16, 21, 22, 26-32, 50-97, and 101 are pending in the present application, claims 11 and 98-100 having been cancelled and new claim 101 added by the above amendments.

Claims 1, 2, 21, 50, 61, 78, 79, and 82 have been amended to remove references to "pharmaceutical" use.